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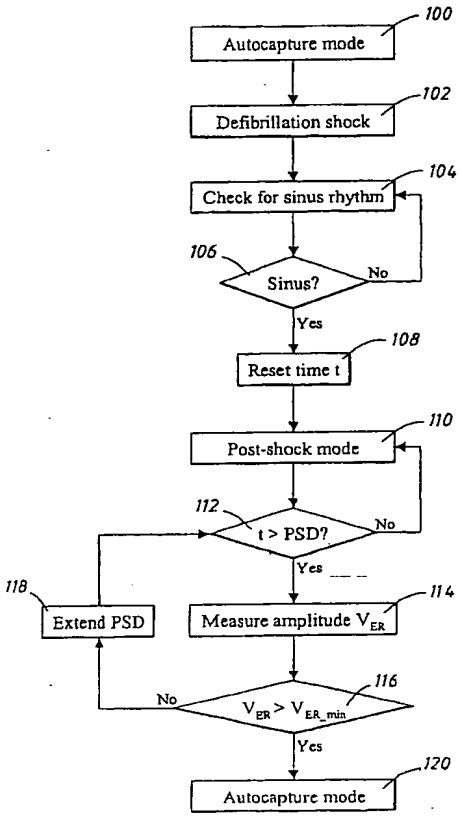
(54) Title: IMPLANTABLE CARDIOVERTER DEFIBRILLATOR



(57) Abstract: An implantable cardioverter defibrillator having an autocapture mode of operation. Following the delivery of a defibrillation shock, the ICD is arranged to switch from an autocapture mode of operation to a post-shock mode of operation, in which the ICD utilizes predetermined pacing pulse parameter settings. Following the expiry of a preprogrammed time interval, which may be extendable, the ICD switches back to the autocapture mode of operation.

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IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

Technical field

The present invention generally relates to the field of implantable cardioverter defibrillators. More specifically, the invention relates to an implantable cardioverter defibrillator (ICD) including a system arranged for automatic capture threshold determination.

Background art

Heart defibrillation is currently performed by the discharge of a powerful voltage pulse between two electrodes. The electrodes are placed so the discharge takes place over the heart or a large part thereof. The energy in a pulse amounts typically from a few joules up to a few dozen joules.

In order to reduce pacing energy consumption and increase longevity, methods for automatic capture threshold determination, or automatic regulation of pacing pulse settings, may be provided in cardiac stimulators for maintaining the energy of the stimulation pulses at a level just above what is needed to effectuate capture. One such method is known as the AutoCapture™ Pacing System. See also WO 99/65566. Longevity is increased because automatic capture detection allows pacing at lower energies without compromising patient safety. It is also known in the art to provide automatic capture pacing in an ICD system, see e.g. US 6,327,498.

The autocapture functionality of the AutoCapture™ Pacing System automatically adapts the stimulation output to the minimal energy required to capture the heart. After each single delivered pacing stimulus, capture is verified. The verification is based on detection of the Evoked Response (ER), which is defined as the electrical response of the myocardium to a pacing stimulus. During a time window after an emitted pacing pulse, sensing circuitry of the heart stimulator looks for an evoked re-

sponse. In case an evoked response is not detected during the detection window, the heart stimulator interprets this as loss of capture and a back-up pulse of higher energy is emitted at the end of the detection window. On the other hand, if an evoked response is detected capture is verified.

If two consecutive losses occur, then a threshold search will be performed in order to evaluate whether the pacing threshold has changed. If necessary, the pacing pulse settings will be adjusted such that subsequent pacing pulses will have a higher energy content as compared to the energy content of the two consecutive pulses that did not effect an evoked response. The process of changing the energy content in the pacing pulses is referred to as a threshold search. In this process, the energy content in the pacing pulses is adjusted in steps and capture is verified for each pacing pulse. After the threshold has been determined, a working margin is added to the measured threshold in order to determine the new pacing pulse settings following the threshold search. This working margin is typically in the order of 0,3 V.

The above discussed threshold search is caused by an increased threshold and will be executed immediately when two consecutive losses of capture has been detected. If the pacing threshold is stable for a longer period of time and no sudden changes occur, i.e. there is no consecutive losses of capture, then threshold searches will be initiated by a timer at regular intervals. These intervals are typically in the order of eight hours. This will allow for the pulse generator to adapt to threshold changes regardless of whether the threshold increases or decreases.

The large energy required in a defibrillation shock, e.g. an ICD shock, has shortcomings as regards the longevity of an ICD device. Furthermore, the powerful energy discharge in the ICD shock has adverse effects on the organism. For instance, it is known that the pacing or cap-

ture threshold is increased immediately following a defibrillation shock. Furthermore, the length of the depolarization phase may also be affected, as well as the length of the refractory period of the myocardium.

Thus, the results of automatic capture threshold detection, below simply referred to as autocapture, immediately following an ICD shock may differ considerably from the results of autocapture provided when the myocardium is not affected by a recent ICD shock, which may have an adverse effect on the accuracy of the autocapture measurements. For instance, autocapture measurements immediately following the delivery of a shock may result in a higher pacing threshold. The resulting higher pacing output will be used until the next threshold search is initiated by the timer. Furthermore, polarization from the pacing electrode may become modified immediately following the delivery of a shock. This can result in changes in the sensing signal used for detecting capture following a shock.

Summary of the invention

The object of the present invention is to provide an implantable cardioverter defibrillator in which the above stated drawbacks are reduced or eliminated.

This and other objects are achieved according to the present invention by providing an ICD having the features defined in the independent claims. Preferred embodiments are defined in the dependent claims.

For the purposes of this application, it should be noted that there are a plurality of different methods for providing automatic capture detection, or automatic pacing pulse settings, known in the art, apart from the one described above. Autocapture mode of operation includes the following elements: a) detection of whether a delivered stimulation pulse has captured the heart or not, b) delivery of a back-up pacing pulse within a short period following a pacing pulse that did not capture the heart,

and c) ability to determine the pacing threshold. The term "autocapture" referred to in the following relates to all such methods providing elements a-c mentioned above. In other words, the present invention is not restricted to an ICD having the particular autocapture functionality described above.

Thus, the present invention is based on the idea of providing an ICD having autocapture functionality with the ability to switch from an autocapture mode of operation to a post-shock mode of operation with predetermined pacing pulse settings following the delivery of a cardioversion or defibrillation shock. In other words, the autocapture mode of operation is paused following the delivery of a cardioversion or defibrillation shock. This will result in elimination of any adverse effects that may occur if autocapture is enabled immediately following a shock.

According to the present invention, the ICD is arranged to enter a post-shock operating mode following the delivery of a cardioversion or defibrillation shock, in the continuing simply referred to as the delivery of a shock. In the post-shock operating mode, the ICD utilizes predetermined parameter settings for the pacing or stimulating pulses.

In a first example, these settings can be programmed by the surgeon in connection with the implantation surgery, and thus preferably be based on capture threshold measurements conducted in connection with said surgery.

In a second example, the ICD could utilize predetermined pacing pulse settings that were programmed in connection with the manufacture or assembly of the ICD, i.e. before delivery of the ICD to the hospital where the implantation is to take place.

In a third example, the parameters of the predetermined pacing pulse settings could be programmed or adjusted after implantation and be based on pacing events measured during the every-day use of the ICD and stored

in the ICD for later evaluation. Any combination of these examples are also conceivable without departing from the scope of the invention. In other words, the term "predetermined pacing pulse parameters" should be interpreted as being predetermined at the delivery of the shock.

According to preferred embodiments of the invention, the ICD is arranged to enter the post-shock operating mode first after the detection of sinus rhythm following the delivery of a shock.

Furthermore, the ICD is arranged to return from the post-shock operating mode to the autocapture mode following a certain time interval, below referred to as post-shock duration. According to exemplifying embodiments of the invention, the post-shock duration is preprogrammed. Preferably, the post-shock duration is in the range of 1-15 minutes, more preferably in the range of 5-10 minutes. Following the expiry of the preprogrammed post-shock duration, the ICD is arranged to automatically return to the autocapture operating mode.

According to further embodiments of the invention, the time interval during which the ICD is operating in the post-shock operating mode may be extendable. For example, before the first predetermined time interval following a shock has expired, the ICD is arranged to perform measurements of selected cardiac parameters and to evaluate whether the time interval is to be extended.

Preferably, if post-shock duration is indeed extended, the ICD is arranged to repeat said measurement prior to the expiry of the thus extended post-shock duration, and to evaluate whether the extended post-shock duration should be extended even further. This may be repeated until the evaluation indicates that the post-shock duration shall not be further extended, or until the number of extensions, or the accumulated post-shock duration time, reaches a predetermined maximum post-shock duration limit. In the earlier case, the ICD returns to the autocapture operating mode following the expiry of the pres-

ent time interval. However, in the latter case, the ICD could be returned to the autocapture operating mode, or maintain the post-shock operating mode until the ICD has been evaluated and, possibly, re-programmed by a physician during a follow-up.

According to one exemplifying embodiment, said cardiac parameters include the amplitude of a heart activity signal measured by sensing circuitry of the ICD, e.g. the evoked response signal. Then, if the amplitude of the measured signal for instance exceeds or is less than a predetermined threshold value, the time interval is extended, preferably by a preprogrammed extension interval. Said cardiac parameters could also include the morphology or the polarization of the evoked response signal. For instance, the cardiac signal amplitude and morphology should not deviate too much from the cardiac signal amplitude and morphology before the delivery of a shock. Likewise, the polarization of the evoked response signal following a shock should be close to the polarization of the evoked response signal preceding the shock.

Preferably, said cardiac parameters are continuously monitored and stored, such that the measured parameters following a shock may be compared to the values of said parameters prior to the delivery of a shock. If the difference between the pre-shock and the post-shock parameters exceeds a predetermined threshold value, then the time interval may be extended.

According to exemplifying embodiments of the invention, the duration of said preprogrammed extension interval is fixed, and preferably in the range of 2-15 minutes, more preferably in the range of 5-10 minutes. According to alternative embodiments of the invention, said extension interval, although preprogrammed, may be varied. As an example, a first extension interval could be in the range of 2-5 minutes, a second in the range of 3-8 minutes, a third in the range of 5-15 minutes, a fourth in the range of 10-30 minutes, etc. Thus, the first ex-

tension interval, or initial post-shock duration, can be made very short in order for the ICD to return to the autocapture mode of operation as quickly as possible, while simultaneously not having to repeat the measurements and evaluations more often than necessary. In this embodiment, the initial post-shock duration immediately following a delivered shock is preferably short, for example in the range of 1-5 minutes.

The pacing parameters that may be adjusted to predetermined pacing pulse settings when the ICD switches to a post-shock operating mode can for example include the base rate, the pacing pulse amplitude, the pacing pulse width, and the P/R-wave sensitivity. Said pacing parameters could relate to either ventricular or atrial pacing pulses, or to both ventricular and atrial pacing pulses.

According to exemplifying embodiments of the present invention, and without departing from the scope of the present invention, the ICD may be arranged for terminating a ventricular or an atrial arrhythmia or fibrillation, respectively, or both. Furthermore, the ICD may be arranged for delivering ventricular or atrial pacing pulses, respectively, or both. Also, the autocapture functionality referred to throughout this application may be applied to atrial pacing pulses, as well as to ventricular pacing pulses. According to an exemplary embodiment of the present invention, the ICD utilizes a single ventricular lead for delivering both defibrillation and cardioversion shocks to a ventricle of the heart, as well as for delivering the ventricular pacing pulses. Such an implantable lead is disclosed in US 6,327,498, which is incorporated herein by reference in its entirety. This configuration also enables autocapture detection using one and the same lead.

According to other exemplary embodiments, the defibrillation and cardioversion shocks may be delivered through one lead, and the pacing pulses may be delivered through another lead, either ventricular or atrial. Then,

the lead for pacing is preferably also used for sensing capture.

As understood by the skilled person, any defibrillation or cardioversion shock sequence may be used without departing from the scope of the present invention. For instance, the cardioversion may be in accordance with a stepped cardioversion algorithm, such as shown in US 5,620,469. Another example can be found in EP 588 125, which discloses an apparatus for defibrillating a human heart using a sequence of combined pacing pulses and defibrillation shocks.

Further objects and advantages of the present invention will be discussed below by means of exemplary embodiments.

Brief description of the drawings

Exemplifying embodiments of the invention will be described below with reference to the accompanying drawings, in which:

Fig. 1 is a diagrammatic, perspective view of an ICD system according to the present invention;

Figs. 2 and 3 are schematic illustrations of an ICD according to alternative embodiments of the present invention; and

Fig. 4 is a flow diagram illustrating the operation of the ICD according to an embodiment of the present invention following the delivery of a cardioversion or defibrillation shock.

Description of preferred embodiments

With reference first to Figs. 1 and 2, a first embodiment of an implantable defibrillation system of the present invention is generally shown and comprises an implantable cardioverter defibrillator (ICD) 10, typically subcutaneously implanted between the skin and the ribs of the patient. An implantable, ventricular ICD lead system 24 is passed through a vein into the right ventricle 2 of

a heart 1. The distal end of the lead system 24 has a tip electrode 28 contacting the interior of the ventricle, preferably at its apex 4.

According to the described embodiment, an elongated, annular shocking coil electrode 26, also referred to as a ring electrode, is spaced at a distance of about 1.5-3.0 cm from the tip electrode 28. The shocking coil extends in a direction towards the region of the tricuspid valve 6 between the right atrium 8 and the right ventricle 2 and typically has a length of about 2-6 cm.

Each of these electrodes is connected, via the ventricular lead 24, to the circuitry contained in the ICD 10. The metallic enclosure or "can" of the ICD 10 also forms an electrode surface 20.

A variety of lead configurations can be used in order to pace the heart, to sense the intrinsic depolarizations of the heart, and to deliver defibrillation or cardioversion shocks to the heart. However, according to a first embodiment of the invention, there is disclosed a configuration where ventricular pacing and sensing are accomplished using the tip electrode 28 and the shocking coil electrode 26 of the ventricular lead 24. Defibrillation is delivered using the shocking coil electrode 26 and the can electrode 20. Thus, the ventricular lead 24 may be utilized both for ventricular pacing and as a defibrillator lead. According to a second embodiment, however, both ventricular pacing and defibrillation is delivered using the shocking coil electrode 26 and the can electrode 20.

According to a further embodiment, the lead comprises two ring electrodes as well as a tip electrode, for instance as described in the above-mentioned US 6,327,498, which is incorporated herein by reference. Then, defibrillation is delivered using one ring electrode and the can, and pacing is delivered using the other ring electrode and the can.

The ICD 10 comprises a can 20, as mentioned above, which also acts as an electrode. The can 20 contains a pulse generator 12 for delivering pacing pulses, sensing circuitry 14 for detecting ventricular evoked response or capture, and a defibrillation unit 16 for delivering cardioversion and/or defibrillation shocks. The ventricular lead 24 is connected to each of these units via a header attached to the can 20. Furthermore, the can 20 also contains a control unit 18 arranged for receiving and processing sensing information from said sensing circuitry 14, and for controlling said pulse generator 12 and said defibrillation unit 16, thereby also controlling the timing and delivery of pacing pulses, cardioversion shocks and defibrillation shocks to the heart.

For the purposes of the present invention, use can be made of sensing circuitry, pulse generators and defibrillation and cardioversion units that are known per se. Since the outlines and functions of said elements are familiar to the person skilled in the art, they will not be described in further detail herein.

In Fig. 3, there is shown an alternative embodiment of the present invention. According to this embodiment, the ICD system also comprises an atrial lead 22, which has a similar configuration as the ventricular lead 24 described above. Thus, the atrial lead 25 also comprises a tip electrode and a ring electrode spaced apart from the tip electrode. The tip electrode of the atrial lead 22 is positioned in the atrium of the heart 1, as is schematically depicted in Fig. 3.

Furthermore, as is the case with the ventricular lead 24, the atrial lead 22 is also connected to the pacing, sensing and defibrillation units via the header of the ICD 10, wherein the sensing circuitry 12 is further arranged for sensing atrial capture, the pulse generator 14 is further arranged for delivering atrial pacing pulses, and the defibrillation unit 16 is further arranged for delivering atrial defibrillation shocks.

Turning now to Fig. 4, the function of the ICD will be described, in particular in relation to the embodiment of the present invention as shown in Figs 1 and 2, i.e. with a ventricular lead only. It should be noted, however, that the present invention is equally applicable to the embodiment of Fig. 3.

First, at step 100, the ICD is in its normal mode of operation, namely the autocapture mode. In this mode, the ICD is arranged to perform automatic capture threshold determinations, e.g. in accordance with the AutoCapture™ Pacing System. In this operating mode, capture is verified based on detection of the evoked response (ER) by the sensing circuitry 14 after each single delivered pacing stimulus.

If an evoked response is detected, capture is verified. Failure to detect an evoked response is interpreted as a loss of capture, and a higher energy pacing pulse is delivered as a back-up. If this is immediately followed by another failure to detect an evoked response, then a threshold search is performed. If the threshold search indicates an increase in the capture threshold, then the control unit 18 adjusts the pacing pulse settings by increasing the amplitude for subsequent pacing pulses. Again, a back-up pulse of higher energy is delivered to compensate for the pacing pulse that did not effect any evoked response.

If, for a longer period of time, there are no consecutive failures to detect an evoked response, then a threshold search will be performed every eight hours.

In step 102, a defibrillation shock is delivered in order to terminate ventricular tachycardia and/or fibrillation. This step is of course preceded by the detection of ventricular tachycardia or fibrillation. However, for the purposes of the present invention, use can be made of means and measures well known to the person skilled in the art for detecting tachycardia and/or fibrillation. Thus, a detailed description thereof is not required for

the understanding of the present invention and is therefore not provided herein.

Following the delivery of the defibrillation shock, the sensing circuitry 14 checks, at step 104, whether the heart resumes its natural sinus rhythm. When sinus rhythm has been confirmed, at step 106, the control unit 18 switches, at step 110, the mode of operation for the ICD 10 from the autocapture mode to a post-shock mode of operation. The post-shock mode is maintained during a preprogrammed time interval, below referred to as post-shock duration PSD. The time count is reset at step 108 immediately prior to the entry into the post-shock mode.

If it is determined at step 106 that no sinus rhythm is present and that fibrillation still occurs, then the ICD 10 delivers further defibrillation shocks until the defibrillation is successful. For ease of description, this has not been illustrated in Fig. 4, but is readily understood buy the person skilled in the art.

In the post-shock mode, the parameter settings for the pacing pulses delivered by the ICD 10 are adjusted by the control unit 18 to predetermined values. In one example of a preferred embodiment of the invention, the pacing pulse width is adjusted to a predetermined value in the range of 0.5-1.5 ms, and the pacing pulse amplitude is adjusted to a predetermined value in the range of 2.5-7.5 V.

The predetermined pacing pulse parameters may be adapted to the characteristics of the heart of the particular patient in which the ICD is implanted. Furthermore, the parameters for the predetermined pacing pulse settings may also be adjusted after implantation of the ICD, e.g. by a physician during regular follow-ups , in adaptation to physiological changes in the patient.

The post-shock duration is in Fig. 4 denoted as PSD. In this embodiment, the initial post-shock duration is in the range of 5-10 minutes. However, both longer and shorter intervals are conceivable. At step 112, it is de-

termined whether post-shock duration has expired. If this is the case, the sensing circuitry 14 measures one or more selected characteristics of the heart signal, in this case the amplitude of the evoked response or the intrinsic heart beat. However, other characteristics may also be contemplated. The measurement is performed in order to determine whether the myocardium still suffers the effects of the delivered high energy defibrillation pulse to an extent that renders the autocapture mode of operation unsuitable.

Then, the control unit 18 evaluates the measured parameter of the heart signal, here the amplitude V_{ER} of the evoked response signal, and determines, at step 116, whether the amplitude V_{ER} exceeds a predetermined threshold value V_{ER_min}, which is an indication that the evoked response signal is no longer affected by the effects of the delivered shock. If so, the control unit switches, at step 120, the ICD back to the autocapture mode and the normal operation of the ICD is resumed.

However, if the amplitude V_{ER} does not exceed the threshold value V_{ER_min}, i.e. the evoked response signal is still affected by the shock and the cardiac tissue has not yet recovered from the effects of the delivered shock, then the post-shock duration PSD is at step 118 extended by a predetermined time interval. The algorithm is then returned to the loop of steps 110 and 112 until the expiry of the extended post-shock duration. Following the expiry thereof, the amplitude V_{ER} is once again measured to determine whether the ICD can be switched back to the autocapture mode. In the illustrated embodiment, this is repeated until the amplitude V_{ER} exceeds the threshold value V_{ER_min}.

In another example, not shown, the amplitude V_{ER} may alternatively or additionally be compared with a highest threshold value. Then, the ICD is switched back to the autocapture mode when the amplitude V_{ER} no longer exceeds the highest threshold value.

Furthermore, the ICD is in one embodiment provided with a maximum post-shock duration limit, or a limit of the number of times that the post-shock duration may be extended. Then, the ICD may switch to the post-shock mode permanently, or to another mode of operation adapted to the case where the heart signal amplitude is permanently increased. The ICD may then be re-programmed by a physician during the next follow-up.

According to the illustrated embodiment, the PSD is extended with the same time interval as the initial post-shock duration, i.e. in the range of 5-10 minutes. However, for other embodiments of the present invention, the extension of the PSD may be selected to be longer or shorter. For still further embodiments, the extension of the PSD may be varied, depending on whether the post-shock duration is extended for the first, second, or third time, etc.

According to yet another embodiment, the predetermined post-shock duration is fixed. In this embodiment, the control unit 18 switches the ICD 10 back to the autocapture mode immediately following the check of the expiry of the post-shock duration at step 112, i.e. steps 114 and 116 are omitted. According to this embodiment, the fixed post-shock duration PSD is in the range of 5-15 minutes, more preferably approximately 10 minutes.

According to further embodiments of the invention, and with reference to Fig. 3, the ICD is also arranged for delivering atrial pacing pulses to the atrium of a human heart. As readily understood by the person skilled in the art, the description above with reference to Fig. 4 is equally applicable to the embodiment shown in Fig. 3, regardless of whether it is ventricular or atrial fibrillation that is to be terminated. Thus, following the delivery of a defibrillation shock, the control unit switches the ICD from an autocapture mode to a post-shock mode of operation, in which the atrial pacing pulse set-

tings are adjusted to predetermined pacing pulse parameter values.

In this embodiment, the atrial pacing pulse settings, i.e. pacing pulse width and amplitude, equals that of the ventricular pacing pulse settings described above. Thus, the pacing pulse width is adjusted to a specific predetermined value in the range of 0.5-1.5 ms, and the pacing pulse amplitude is adjusted to a specific predetermined value in the range of 2.5-7.5 V. Furthermore, the criteria for reverting from the post-shock mode to the autocapture mode are the same as described above with particular reference to Figs 1, 2 and 4. In this respect, it must however be noted that the predetermined atrial pacing pulse settings could also differ from the predetermined ventricular pacing pulse settings.

As readily understood by the skilled person, it should be noted that the above described means for terminating ventricular tachycardia and/or fibrillation, as well as the means for terminating atrial tachycardia and/or fibrillation, may be comprised in a single ICD, such as the ICD described with reference to Fig. 3.

In yet another embodiment of the present invention, the ICD 10 is provided with an atrial lead 22 only, i.e. there is no ventricular lead. Thus, the ICD 10 is only capable of pacing, sensing and terminating fibrillation or flutter in the atrium of the heart. In a still further embodiment, the ICD 10 has an atrial lead for pacing and terminating fibrillation or flutter in the atrium, but is also provided with a ventricular lead for sensing in the ventricle of the heart. However, it must be noted that since the present invention is not restricted to ventricular pacing or fibrillation, the detailed description above of preferred embodiments for carrying out the present invention applies equally to these two embodiments.

Although specific embodiments have been shown and described herein for purposes of illustration and exemplification, it is understood by those of ordinary skill

in the art that the specific embodiments shown and described may be substituted for a variety of alternative and/or equivalent implementations without departing from the scope of the present invention. Consequently, the present invention is defined by the wordings of the appended claims and equivalents thereof.

CLAIMS

1. An implantable cardioverter defibrillator (ICD) (10) including a system arranged for an autocapture mode of operation, the system comprising:

a pulse generator (12) for delivering pacing pulses to at least one chamber of a heart (1), a defibrillation unit (14) for delivering cardioversion or defibrillation shocks to at least one chamber of said heart (1), sensing circuitry (16) for sensing heart activity, both intrinsic and resulting from capture following a delivered pacing pulse, and a control unit (18) for controlling the timing and energy of said pacing pulses and cardioversion and defibrillation shocks, respectively,

wherein the system has a first operating mode arranged for said autocapture mode of operation,

characterized in that the system has a second operating mode arranged for delivering pacing pulses according to predetermined pacing pulse settings,

wherein the control unit is arranged for switching the system from said first operating mode into said second operating mode following a delivery of a cardioversion or defibrillation shock.

2. The ICD as claimed in claim 1, wherein said control unit is arranged for switching the system back to said first operating mode following a predetermined time interval.

3. The ICD as claimed in claim 2, wherein said predetermined time interval is in the range of 1-15 minutes, preferably in the range of 5-10 minutes.

4. The ICD as claimed in claim 1, wherein said control unit is arranged for switching the system back to said first operating mode following an extendable time interval,

wherein the sensing circuitry is arranged for measuring, when sensing capture or intrinsic heart activity following a shock, signal characteristics of a sensed heart activity signal, and

wherein the control unit is arranged for extending said extendable time interval on the basis of said measured characteristics.

5. The ICD as claimed in claim 4, wherein said extendable time interval comprises a predetermined basic time interval, and wherein the sensing circuitry is arranged for measuring said signal characteristics prior to the expiry of said basic time interval, thereby enabling the control unit to extend said extendable time interval prior to the expiry of said basic time interval with an extension time interval.

6. The ICD as claimed in claim 5, wherein the sensing circuitry and control unit are arranged for measuring said signal characteristics and extending said extendable time interval with a further extension time interval prior to the expiry of each extension time interval.

7. The ICD as claimed in claim 5 or 6, wherein said extension time interval is in the range of 5-15 minutes, preferably 10 minutes.

8. The ICD as claimed in any one of claims 5-7, wherein said basic time interval is in the range of 1-15 minutes, preferably in the range of 5-10 minutes.

9. The ICD as claimed in any one of claims 4-8, wherein said characteristics comprise the amplitude of the heart activity signal.

10. The ICD as claimed in any one of the preceding claims, wherein said pulse generator is arranged for delivering pacing pulses to a ventricle of the heart.

11. The ICD as claimed in any one of the preceding claims, wherein said pulse generator is arranged for delivering pacing pulses to an atrium of the heart.

12. The ICD as claimed in any one of the preceding claims, wherein said defibrillation unit is arranged for delivering cardioversion and/or defibrillation shocks to a ventricle of the heart.

13. The ICD as claimed in any one of the preceding claims, wherein said defibrillation unit is arranged for delivering cardioversion and/or defibrillation shocks to an atrium of the heart.

Fig. 1

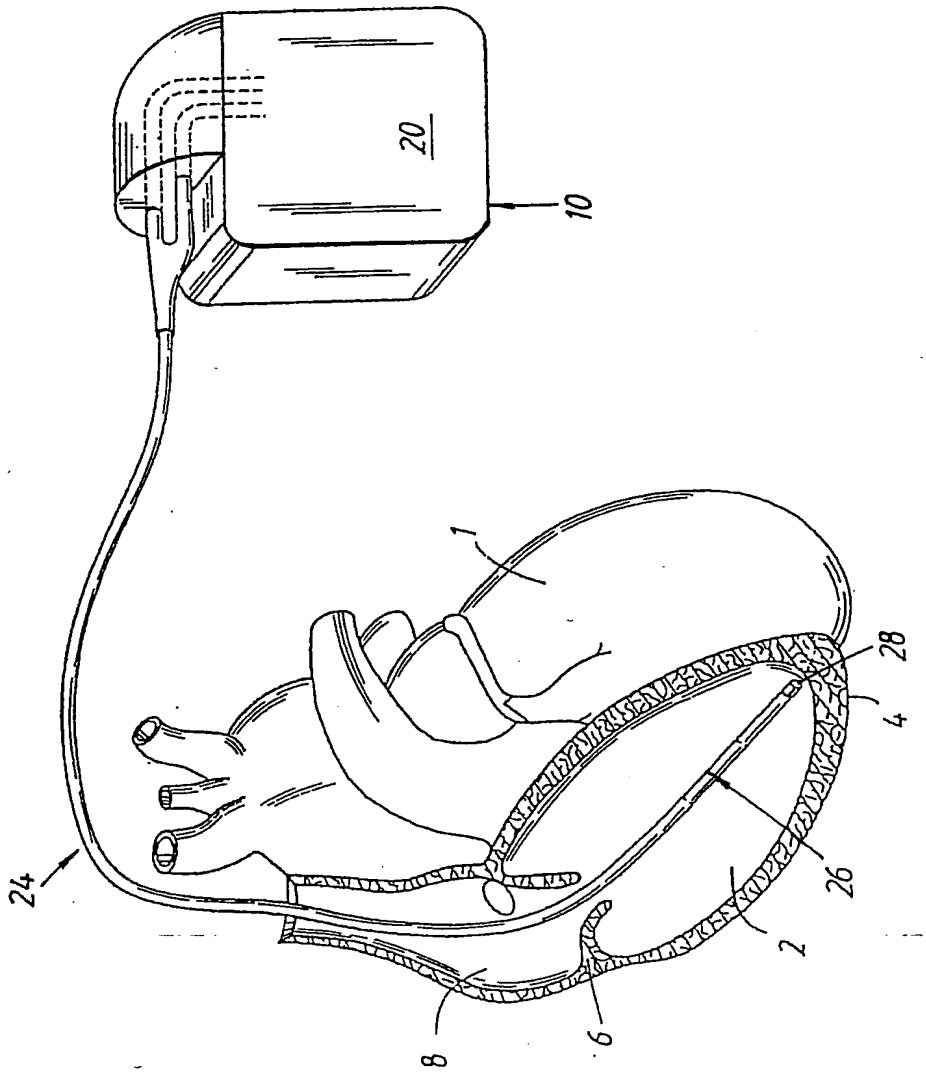


Fig. 2

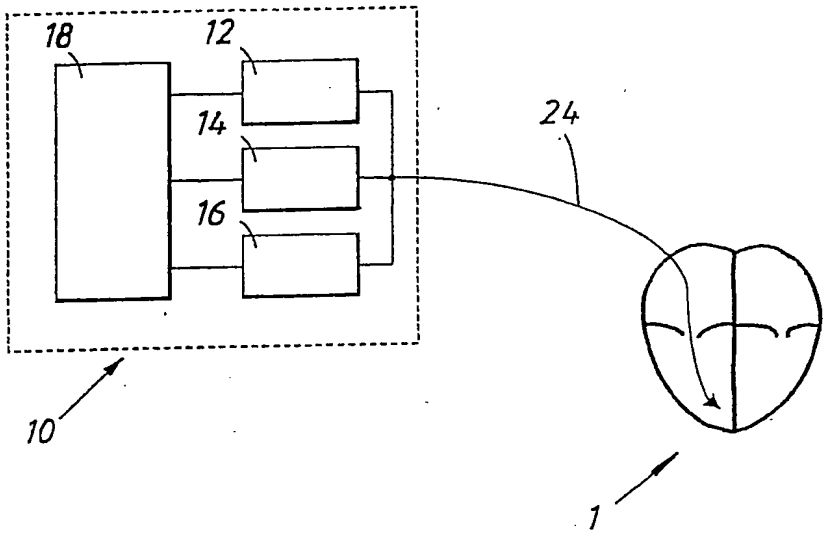


Fig. 3

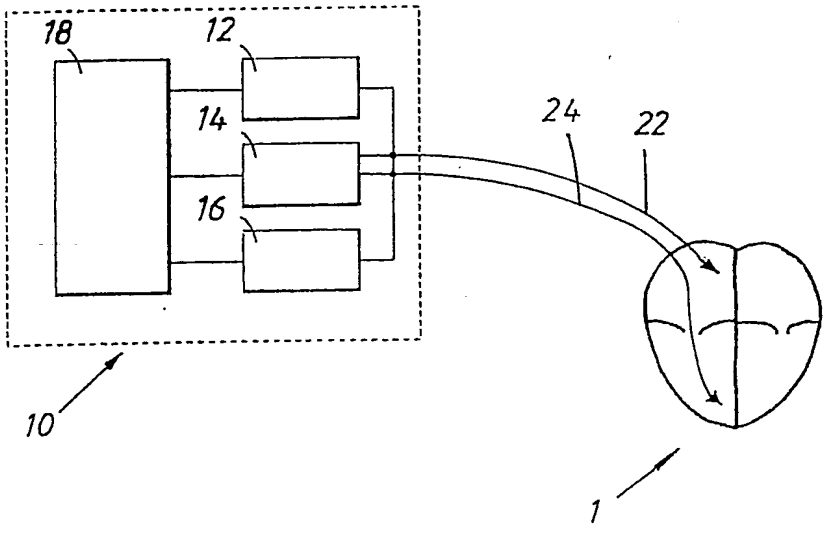
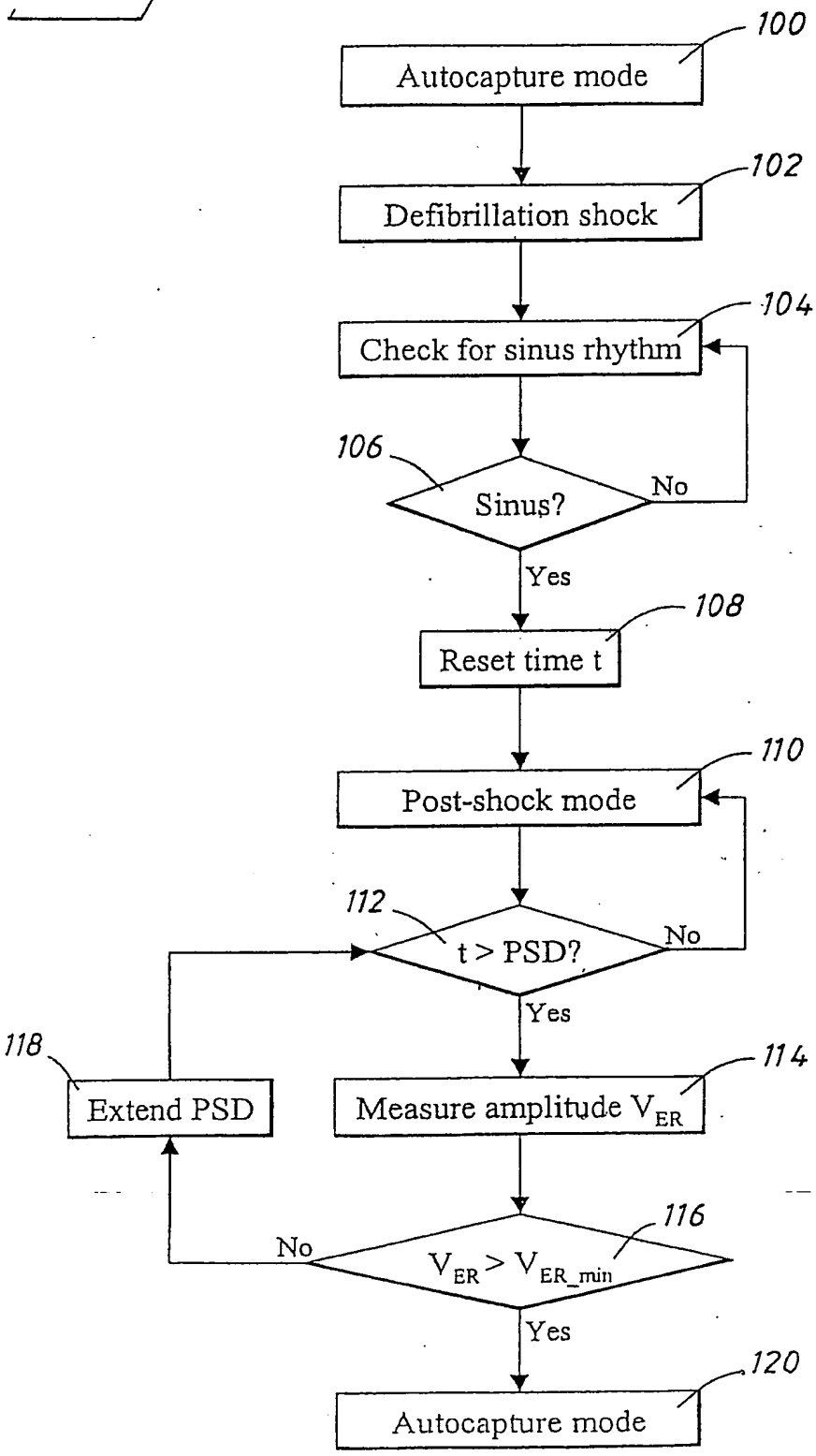


Fig. 4


100
Autocapture mode
102
Defibrillation shock
104
Check for sinus rhythm
106
Sinus?
No
Yes
108
Reset time t
110
Post-shock mode
112
t > PSD?
No
Yes
118
Extend PSD
114
Measure amplitude V_{ER}
116
$V_{ER} > V_{ER\_min}$
No
Yes
120
Autocapture mode

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/01297

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/365, A61N 1/39 // A61N 1/05
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ, MEDLINE, INSPEC, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4869252 A (GILLI, N.L.), 26 Sept 1989 (26.09.89), column 2, line 11 - column 3, line 28 --	1-13
A	US 6430441 A (LEVINE, P.A.), 6 August 2002 (06.08.02), abstract --	1-13
A	US 6157859 A (ALT, E.), 5 December 2000 (05.12.00), abstract --	1-13

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 October 2003	28 -10- 2003
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Anna Malmberg /OGU Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/01297

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WELCH, P.J. et al. "The Effect of Biphasic Defibrillation on the Immediate Pacing Threshold of a Dedicated Bipolar, Steroid-Eluting Lead". PACE, August 1999, Vol. 22, pages 1229 - 1233, abstract -- --------	1-13

INTERNATIONAL SEARCH REPORT

Information on patent family members

06/09/03

International application No.
PCT/SE 03/01297

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4869252 A	26/09/89	DE 68924490 D,T	30/05/96
		EP 0324604 A,B	19/07/89
US 6430441 A	06/08/02	EP 1118351 A	25/07/01
US 6157859 A	05/12/00	US 6073049 A	06/06/00
		CA 2255653 A	20/11/97
		EP 0906137 A	07/04/99
		JP 2000510733 T	22/08/00
		US 5725559 A	10/03/98
		WO 9743004 A	20/11/97